APPARATUS AND METHOD TO STOP BLEEDING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of co-pending application

U.S. patent application Ser. No. 14/819,383, filed Aug. 5, 2015, which claims the benefit of the earlier filing dates of the following applications

U.S. patent application Ser. No. 13/941,219, filed Jul. 12, 2013;

U.S. Provisional Patent Application No. 62/089,281, filed Dec. 9, 2014;

U.S. Provisional Patent Application No. 62/096,857, filed Dec. 25, 2014;

U.S. Provisional Patent Application No. 62/103,063, filed Jan. 13, 2015;

U.S. Provisional Patent Application No. 62/142,195, filed Apr. 2, 2015;

U.S. Provisional Patent Application No. 62/157,419, filed May 5, 2015.

FIELD

Embodiments described herein concern devices and methods for obtaining hemostasis after puncturing a blood pathway, including without limitation puncture of radial or ulnar artery.

BACKGROUND

Blood vessel puncture is commonly needed for performance of endovascular procedures. Smaller caliber arteries, including radial, ulnar and pedal arteries, are easier to manage after the procedure because bleeding can be controlled more easily with external pressure. However, occlusion of these arteries occurs more frequently compared to larger arteries, which frequently results in permanent loss of patency.

Radial artery occlusion refers to the blockage of the radial artery and is a consequence of radial artery cannulation that obliterates the radial artery lumen. Hemostatic devices, which are attached by being wrapped around the portion of an arm where the puncture site (also referred to as the access site) is located and compress the puncture site where bleeding is to be stopped, are already known in the prior art (e.g., U.S. Pat. No. 7,498,477 B2, U.S. Pat. No. 8,481,803, U.S. Pat. No. 8,481,805, JP 3,031,486 U). In prior-art hemostatic devices, pressure applied to the puncture site may lead to radial artery occlusion making it not available for access in the future.

Radial artery occlusion, after transradial access occurs in 2-10% of patients, and is frequently associated with obliteration of radial artery lumen, making that radial artery not suitable for future access for endovascular procedures, invasive monitoring, or its utility as a bypass conduit. Prevention of radial artery occlusion is of paramount importance to avoid loss of a major source of blood supply, future repeat access and other utilities of radial artery, after transradial access. Maintenance of radial artery flow during hemostatic compression has been shown to lower the risk of radial artery occlusion (PROPHET Trial, Pancholy S et al, Catheterization and Cardiovascular Interventions 2008:72(3); 335-340). A decrease in duration of compression has also been shown to lower the risk of radial artery occlusion (Pancholy S et al, Catheterization and Cardiovascular Interventions 2012:79(1):78-81). Thus maintaining blood flow in the radial artery, while compressing the access site after instrumentation, is known to reduce the risk of post-instrumentation radial artery occlusion. Patent hemostasis is therefore understood to mean achieving the cessation of bleeding at the cannulation wound (access site) of the radial artery, while blood is allowed to flow through that artery.

In an article entitled Efficacy and Safety of Transient Ulnar Artery Compression to Recanalize Acute Radial Artery Occlusion After Transradial Catheterization (Am J Cardiol 2011; 107:1698-1701) Ivo Bernat, M D and others discuss a method directed to open an occluded radial artery after the radial artery becomes occluded. In this study, in patients with radial artery occlusion, 3-4 hours after hemostasis of the radial artery, ulnar artery compression was applied to attempt recanalization of radial artery. Bernat et. al. achieved higher success rates at reopening of the radial artery by administration of heparin and compression of the ipsilateral ulnar artery.

SUMMARY

Transradial, as well as transulnar, puncture is increasingly used for obtaining vascular access for endovascular procedures. In one embodiment, a hemostatic device comprises two balloons wherein, after transradial access, the bleeding from the radial artery is stopped by compressing the radial artery at the puncture site using inflation of a first balloon and the radial artery flow is increased by occlusive compression of ipsilateral ulnar artery using inflation of a second balloon. The method maintains blood flow in the radial artery while compressing the access site, after removal of catheter, thereby reducing the risk of post-instrumentation radial artery occlusion. In one embodiment, the first balloon is located over the radial artery to cover a puncture site that is generally about 2 cm. from the base of a palm, and the second balloon is located over the ulnar artery at a position proximate to the base of the palm (Guyon's canal) thereby compressing the ulnar artery at a location where it is most accessible for compression.

In another embodiment, two balloons are part of a band and the band is wrapped around a limb. The center of the first balloon and the center of the second balloon are offset from each other in relation to the central line of axis of the band. In yet another embodiment, the first balloon is larger than the second balloon. In another embodiment, the balloons are rectangular in shape. In one embodiment the first balloon extends the entire width of the band. In one embodiment, the width of the band is greater than 40 mm. In another embodiment, the width of the band is greater than 45 mm. In yet another embodiment, the band has a width of about 55 mm.

In another embodiment, the hemostatic device comprises a flexible band adapted to be wrapped and secured around a hand of a patient at a site on the hand where bleeding is to be stopped, a compression member having an inner peripheral side, which compression member is made of a material more rigid than the band, a first balloon provided on the inner peripheral side at a position deviated to the center portion of the compression member in lengthwise direction of the band, and the first balloon is connected to the band by a connector on a side of the first balloon adjacent the center portion of the compression member, wherein the first balloon inflates when a fluid is introduced therein; and a second balloon provided on the inner peripheral side of the compression member at a position deviated to an edge of the compression member from the center portion of the compression member in widthwise direction of the band, and the second balloon is connected to the band by a connector on a side of the second balloon adjacent to the edge of the compression member, wherein the second balloon inflates when a fluid is introduced therein. In